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Assessing Pharma's Constraints, Opportunities, and Investment Options in Global Health R&D: An Analysis of U.S. Pharmaceutical Company SEC 10-K Filings

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Executive Summary

The private sector is the primary investor in health research and development (R&D) worldwide, with investment annual investment exceeding \$150 billion (West et al., 2017a; Jamison et al., 2013), although only an estimated \$5.9 billion is focused on diseases that primarily affect low and middle-income countries (LMICs) (West et al., 2017b). Pharmaceutical companies are the largest source of private spending on global health R&D focused on LMICs, providing \$5.6 billion of the \$5.9 billion in total private global health R&D per year (West et al., 2017a).

Private sector investment choices may simply reflect the most profitable use of funds or the most comfortable risk-return tradeoffs. There are, however, examples of privately funded R&D, blended financing, and public-private partnerships targeting diseases in LMICs. The detailed story, therefore, is likely more complex, with possibilities at the margin for catalyzing more private sector investment by increasing returns, lowering risk, or identifying policy or financial mechanisms to incent R&D funding. We look more closely at these nuances by examining the evidence for five specific disincentives to private sector investment in drugs, vaccines and therapeutics: scientific uncertainty, weak policy environments, limited revenues and market uncertainty, high fixed costs for research and manufacturing, and imperfect markets. Though all five may affect estimates of net returns from an investment decision, they are worth examining separately as each calls for a different intervention or remediation to incentivize expanded investment by private companies.

Our goal of examining these separate components of private sector investment decisions in global health R&D is made challenging by the scarcity and unevenness of publicly available information on private company decision-making. We therefore reference - and check against - multiple sources. An earlier report (West et al., 2017b) draws on consultations with over two dozen experts on global health R&D from multiple sectors and case studies of leading examples of venture capital investments and innovative finance. Anderson et al. (2017) reports on an expansive review of 285 papers from five primary academic search databases, five supplemental search databases, ten private pharmaceutical company websites, and twelve philanthropic and public organizations involved in health R&D worldwide.

This paper reviews a third information source, examining the risk factors, opportunities and stated incentives as reported by private sector pharmaceutical companies that filed 10-K forms with the U.S. Securities and Exchange Commission (SEC) in the year 2016. The sample is comprised of 132 10-K reports collected from a

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comprehensive sample of all 2016 SEC 10-K filings¹ by companies under the SIC code 2834 ('pharmaceutical preparations').² The SEC 10-K reports follow a standard format, including a business section and a risk section which include information on financial performance, investment options, lines of research, promising acquisitions and risk factors (scientific, market, and regulatory). As a result, these filings provide a valuable source of information for analyzing how private companies discuss risks and challenges as well as opportunities associated with global health R&D targeting LMICs.

Because we are interested in whether any investment barriers are particular to global health R&D investments, we categorized research firms in terms of their reported research focus. Based on the World Health Organization (WHO) typology we distinguish between firms that conduct R&D only on Type 1 diseases (diseases with equivalent or higher burden in high-income relative to lower income countries) and that conduct R&D on at least one Type 2 / Type 3 disease³ (diseases with a greater burden in low- and middle-income relative to high-income countries). The WHO typology uses global burden of disease data from the Institute for Health Metrics and Evaluation (IHME) to determine the ratio of disease burden (measured by DALYs - Disability-Adjusted Life Years) for populations in low- and middle-income countries (LMICs) over the disease burden for populations high-income countries (HICs), and distinguishes disease Types based on this ratio. We reviewed all 10-Ks of firms mentioning R&D on at least one Type 2/3 disease, and a random sample of 61 10-Ks mentioning only Type 1 disease R&D⁴.

Policy Incentives

As reported in Anderson et al. (2017), though a variety of policy tools exist to promote private sector investment in R&D, including push mechanisms (public research funding, R&D tax credits) and pull mechanisms (advance purchase commitments, orphan drug programs, priority review vouchers, and wild-card patent extensions), evidence of effectiveness is mixed. Thus in this review of industry self-reported barriers and opportunities in 10-K filings we further consider the roles that policy tools such as public research funding, R&D tax credits, advance purchase commitments, orphan drug programs, priority review vouchers, and wild-card patent extensions appear to play in catalyzing and sustaining private global health R&D.

In general, these policies apply across a wide range of companies (Table i), but some policies target specific disease Types (Table ii). Most policy incentives are mentioned by firms as having a positive impact on their R&D investments. R&D tax credits are the most commonly mentioned policy tool: 39 of 61 companies working only on Type 1 diseases mention R&D tax credits, compared to 15 of 71 companies working on at least some Type 2 or 3 disease R&D. Orphan drug status is the most commonly mentioned policy tool among companies researching Type 2 or 3 diseases, though it is more often mentioned with regard to Type 1 diseases that those companies work on. Priority review vouchers (a form of expedited review) are mostly mentioned by companies focused in Type 2 or Type 3 disease R&D but are also mentioned by companies involved in biodefense R&D. Advanced Purchase Commitments are not frequently mentioned.

¹ 10-K filings from fiscal year 2016 were used after initial search encompassing more years. Depending on individual company's fiscal year timeline, this could compass only calendar year 2016 or calendar years 2015 and 2016.

² Appendix A includes a summary of firms filing 10-Ks across a larger set of SIC codes that report involvement in some form of global health R&D.

³ Nearly all of these companies (69 of 71) also conduct R&D on at least one Type 1 disease.

⁴ We initially randomly sampled fifty 10-Ks for Type 1 only firms. An additional 11 were added from the sample of firms mentioning at least some Type 2/3 disease R&D, as further review revealed that those firms were not actually pursuing Type 2/3 disease R&D.

Table i. Mentions of policy incentives by impact on company R&D, by company R&D emphasis

Policy Incentive	Positive Impact		Negative Impact		Mixed Impact		Neutral		No Mention	
	Type 1 only	Type 2 or 3	Type 1 only	Type 2 or 3	Type 1 only	Type 2 or 3	Type 1 only	Type 2 or 3	Type 1 only	Type 2 or 3
Advanced Purchase Commitments	0	2	0	0	1	1	0	0	60	67
R&D Tax Credits	39	15	0	0	0	0	0	0	22	56
Orphan Drug Status	25	27	0	0	0	0	0	0	36	44
Expedited Review *	19	23	0	0	0	0	0	0	42	48
505(b)(2)	12	2	4	1	0	1	16	7	29	60
Hatch-Waxman Amendments	17	7	0	0	0	0	16	6	28	58
Other Policies	1	1	0	0	0	0	0	0	60	70

Note: There are a total of 61 companies working solely on Type 1 diseases and 71 companies working on Type 2/3 diseases
 *The Expedited Review category includes Fast Track designation, Priority Review Vouchers, Qualified Infectious Disease Product designation, and Breakthrough Therapy designation

Among specific diseases mentioned in the company 10-Ks, orphan drug designation is mainly referenced in regard to Type 1 or rare diseases affecting high-income countries (Table ii). Expedited review policies mentioned include several aimed specifically at Type 2 or 3 diseases (notably Priority review Vouchers), though others such as “Fast Track” designation may also be applied to Type 1 disease R&D. Overall, expedited review policies are more frequently mentioned specifically for Type 1 diseases than for Type 2 or 3 diseases.

Table ii. Mentions of policy incentives for specific disease R&D investments, by disease type.

	Type 1 diseases (247)	Type 2 diseases (109)	Type 3 diseases (36)
Advanced Purchase Commitments	1%	3%	6%
Orphan Drug Status	25%	7%	11%
Priority Review Vouchers	4%	2%	8%
Expedited Review*	21%	12%	3%
Other Policies	4%	3%	6%

Note: A mention means that the company discussed the policy incentive as referring to a specific disease they were researching in their 10-K report. Hatch-Waxman amendments and R&D tax credits are not included in this table because they are mentioned primarily at the company level and not with respect to specific disease investments.

*The Expedited Review category includes Fast Track designation, Qualified Infectious Disease Product designation, and Breakthrough Therapy designation. Priority Review Vouchers are reported separately.

Investment Constraints and Opportunities

Drawing on Anderson et al. (2017) we evaluate constraints and opportunities to private sector investment in LMIC disease research using a framework derived from public goods theory and theories of private firm behavior, which includes five disincentives hypothesized to inhibit private investment in global health R&D. Most companies mention all five hypothesized disincentive at least once in their 10-K filings, though companies researching at least Type 2 or 3 disease are less likely to mention constraints or opportunities related to these hypotheses (Table ii).

Table iii. Count of companies mentioning each hypothesized disincentive, by company type

Factors hypothesized to affect company investment in R&D	Any Type 2 or 3 R&D (71 companies)		Type 1 R&D Only (61 companies)	
	Mentioned	Not Mentioned	Mentioned	Not Mentioned
1. Scientific Uncertainty	53 (75%)	18	55 (90%)	6
2. Policy and Regulatory Uncertainty	44 (62%)	27	53 (87%)	8
3. Limited Revenues / Market Risk	63 (89%)	8	59 (97%)	2
4. High Costs of Research and Manufacturing*	64 (90%)	7	58 (95%)	3
5. Imperfect Markets**	58 (86%)	13	50 (87%)	11

Note: A mention can be positive, negative, mixed, or neutral.

*Includes up-front costs for the R&D process, manufacturing costs for products of R&D, and discussion of concerns related to securing funding for the R&D process; **Includes licensing agreements

We find more variation of mentions for each hypothesized disincentive at the disease level as compared to the company level (Table iv). At the disease level we only consider hypotheses discussed in the context of a specific disease R&D investment; most hypotheses are mentioned generally by companies and not with reference to a particular disease R&D investment. For Type 1 diseases, the most frequently mentioned hypothesis - limited revenues - is mentioned more than twice as often as the least mentioned hypothesis, policy and regulatory uncertainty. This is similar for Type 2 diseases and Type 3 diseases, although the most frequently mentioned hypothesis for Type 3 diseases are fixed costs followed closely by limited revenues. Policy and regulatory uncertainties are the least mentioned hypothesized disincentive for all disease types.

Table iv. Count of companies mentioning each hypothesized disincentive, by disease type

	Type 1 diseases (247)		Type 2 diseases (109)		Type 3 diseases (36)	
	Mentioned	Not Mentioned	Mentioned	Not Mentioned	Mentioned	Not Mentioned
1. Scientific Uncertainty	141 (57%)	106	35 (32%)	74	8 (22%)	28
2. Policy and Regulatory Uncertainty	65 (26%)	182	12 (11%)	97	3 (8%)	33
3. Limited Revenues / Market Risk	179 (72%)	68	58 (53%)	51	18 (50%)	18
4. High Costs of Research and Manufacturing*	69 (28%)	178	18 (17%)	91	19 (53%)	17
5. Imperfect Markets**	159 (64%)	88	51 (47%)	58	10 (28%)	26

Note: A discussion can be positive, negative, mixed, or neutral.

*Includes up-front costs for the R&D process, manufacturing costs for products of R&D, and discussion of concerns related to securing funding for the R&D process; **Includes licensing agreements

Hypothesis 1: Scientific uncertainty

To what extent are investors deterred by the scientific uncertainty of developing an efficacious and safe therapy that will successfully make it through all clinical trials? This calculation is not unique to global health R&D, except to the extent that Type 2 and 3 diseases are associated with higher scientific uncertainty. Eighty-two percent (108 out of 132) of companies make some reference to scientific uncertainty in the business or risk section of their 10-K filings in 2016, including 75% of companies conducting R&D on some Type 2 or Type 3 diseases (53 out of 71), and 90% of companies focusing exclusively on Type 1 diseases (55 out of 61).

- Some companies (3 in our sample) are developing companion diagnostics alongside their products to increase the chances of success. These diagnostics will lower the risk of clinical trials by allowing researchers to select patients that will better respond to their therapies.
- Three companies report using disease, project, or computer modeling to reduce scientific uncertainty.
- One company uses publicly available information to identify therapies that were pulled off the market for adverse side effects so that it can reevaluate them for its “drug rescue program”.
- Other companies note that novel compounds can lead to more efficacious therapies with fewer adverse side-effects, however, there is more uncertainty as to whether a novel mechanism will result in a marketable product because there is no proof of concept.
- Other mentions include reports that designing studies to evaluate the safety and efficacy of new treatments for rare diseases with no currently available treatment is more difficult because there are no examples of study endpoints to prove efficacy to regulatory agencies.
- Two companies report that complex manufacturing processes have the upside of limiting competition.

Mentions of scientific uncertainty are quite common in 10-K filings relative to expert interviews and the secondary literature. Science was rarely mentioned in West et al. (2017b) and Anderson et al. (2017) found

only four of 285 studies emphasizing the complexity of research, access to existing research or the limited volume of existing knowledge as specific factors influencing private R&D investment decisions.

Hypothesis 2: Policy and regulatory environment

Macroeconomic and policy environments such as regulatory processes, regulatory costs, and weak or uncertain intellectual property (IP) protections - both where products are developed and where they are sold - may discourage private sector investment, particularly for low- and middle- income countries (LMICs). Seventy percent (92 out of 132) of companies in the sample reference policy or regulatory uncertainty in the business or risk section of their 10-K filing, including 62% of companies conducting R&D on Type 2 or Type 3 diseases (44 out of 71) and 87% of companies focusing solely on Type 1 diseases (53 out of 61).

- 86.4% of companies mention the uncertainty of patent and intellectual property rights in boilerplate statements. All five companies that develop products for Type 2/3 diseases and discuss specific negative impacts of weak IP protections, discuss their response to weaker IP systems in markets outside North America and Europe.
- The four companies which discuss health systems and health governance outside the US in detail focus on barriers associated with restrictive health policies or weak regulatory systems.
- One company mentions using Nigeria's regulatory and approval process as a model for submission in other African countries that do not have formal processes.
- Much of the discussion of policy and regulatory uncertainty occurs in general boilerplate language regarding risks and policy pathways open to companies.
- Companies that work on Type 2 and Type 3 diseases are relatively more likely to take advantage of US policies that have larger global reach such as priority review vouchers (PRVs) and fast track pathways. Policies which mainly target Type 1 diseases or products meant for US domestic markets such as Hatch-Waxman Act (dealing with IP rights) are not as widely used for Type 2 and Type 3 diseases or products.

Policy and regulatory environments likewise featured heavily in both expert interviews and the secondary literature review, though with varying specifics. Geo-political risks and unstable macroeconomic and policy environments are widely cited in industry reports as deterrents to private sector investment in global health R&D in West et al. (2017b). In Anderson et al. (2017) uncertainty in returns stemming from the regulatory environment, regulatory costs, and weak or uncertain intellectual property protections are among the more commonly cited policy challenges for private health R&D, rather than general macroeconomic volatility.

Hypothesis 3: Limited revenues and market uncertainty

Developing therapies for small or LMIC markets may not be seen as profitable, either because of a limited ability to pay, weak IP protection to support pricing, limited health care infrastructure to disseminate products, or pricing affected by third-party payers - all reducing the perceived potential for revenue.

Ninety-two percent (122 out of 132) of companies in the sample reference market potential or uncertainty in the business or risk section of their 10-K filing, including 89% of companies conducting R&D on Type 2 or Type 3 diseases (63 out of 71) and 97% of companies focusing solely on Type 1 diseases (59 out of 61).

- Companies (both those targeting Type 1 and Type 2 diseases) strive to differentiate their product candidates from existing products and products in development by other companies as a way of gaining competitive market advantage.
- Two companies describe strategies to create barriers to competition through IP rights and pursuing R&D for diseases with high barriers to entry.

- Companies that research Type 2 and 3 diseases mention market advantages from expanding to markets outside of the United States more often than companies that research Type 1 diseases only.
- Companies that receive reimbursement for their products from national insurance programs, private insurance companies, and other third party payers are not only able to charge higher prices and recover more of their R&D costs but also enjoy a larger market for their products.
- Most companies (both those targeting Type 1 and Type 2 diseases) describe cost containment measures and downward pricing pressure on healthcare expenditures as significant threats to profitability.
- Specific challenges from market competition that both types of companies list are other companies developing drugs for similar indications (33 companies), increasing competition from “biosimilar” drugs (9 companies), the introduction of cheaper generic or OTC drugs (8 companies), well-established existing treatments (3 companies), disease specific competition increasing (4), and competition for government contracts (1 company).

Industry experts, secondary authors, and firm filings all discuss low or uncertain revenues as stifling investment in diseases affecting LMICs. However only two sources cite small market size as the deterrent - most highlight pricing (low and/or uncertain LMIC prices). Incentives to invest in R&D targeting diseases prevalent in the U.S. and other high-income countries are higher given the ability to set prices at what the market will bear, relative to prices in LMICs which may be lower, regulated, or unknown.

Hypothesis 4: High Costs of Research and Manufacturing

Specific concerns related to fixed costs for R&D are mentioned by less than one quarter of the companies in our sample (30 out of 132) and mostly relate to the need to seek out additional sources of funding, but costs and approaches to the manufacturing process for R&D products are mentioned by 98% of companies (129 out of 132). We find that comparable proportions of companies that research Type 1 diseases and Type 2 or 3 diseases discuss positive, negative, and mixed effects of manufacturing costs on research and development.

- Most companies (82%, or 108 out of 132 companies) including both those targeting Type 1 and Type 2/3 diseases in relatively equal numbers, include boilerplate 10-K language reporting the need to ensure additional funding to continue R&D activities.
- Companies report that additional funding from outside sources helps to offset expenditures related to research and development/commercialization of product candidates - additional funding sources discussed are public/philanthropic and other collaborative.
- More companies that research any Type 2/3 diseases reported receiving public funding compared to companies that research Type 1 diseases only.
- Companies that work primarily on diseases that are classified as bio-threats as well as certain Type 3 diseases (especially hemorrhagic fevers) report the U.S. government as the primary purchaser of their product.
- Some companies possess the ability to manufacture small amounts of product, however, scaling up production of products to commercial scale is difficult and comes with risks.
- Outsourcing manufacturing allows companies to avoid expending resources on fixed costs like facilities and instead focus resources on research and development, but problems can arise from limited manufacturers who are able to produce a specific product.
- Manufacturing products internally allows companies to maintain control over processes, “know how” and intellectual property, but facilities can be difficult to finance and use to their full potential.

Similar to scientific uncertainty, cost considerations (as opposed to revenues or local policy environments) are unique to global health R&D only to the extent that Type 2 and 3 diseases are associated with more specific up-front costs than Type 1 diseases. High initial investment costs with difficult to re-purpose capital are often cited as barriers to all health R&D, not particular to global health, reflected in a range of cost estimates for bringing a drug to market between \$802 million and \$2.2 billion (Anderson et al., 2017). In firm filings, however, costs associated with the manufacturing process for R&D outputs are mentioned more than concerns

over upfront specific investments for the R&D process, perhaps because those filing had already incurred such costs.

Hypothesis 5: Imperfect markets

The ability of large firms with downstream capacity to purchase the rights to upstream R&D at a lower cost than producing it internally may reduce incentives for private investment in new global health R&D. Opportunities or constraints related to imperfect markets are mentioned by less than half of all companies for every category of evidence, except for licensing agreements, which are mentioned by 90 out of 134 companies in the sample.

- Type 1 companies in our sample report out-licensing their products more frequently than in-licensing. Type 2/3 companies reported out-licensing their products as frequently as they reported in-licensing. Companies use in-licensing agreements to fill gaps in their research during clinical development, or to gain access to the rights to commercialization and development of a product at the end of (and dependent on the success of) clinical trials.
- Companies most frequently use out-licensing agreements to access global markets, gain revenues to support their R&D base, reduce risks and costs associated with commercialization and marketing, shift disease or product focus, and assist partner companies and organizations in advancing their research.
- Several companies discuss the uncertainties related to their business practice of out-licensing commercialization of their products, noting the risks of giving up rights to a product that would have been more valuable had the company developed it in-house as well as the potential to in-license a product that was riskier than anticipated and does not generate the desired revenue.
- Two companies describe leveraging patent expirations to develop and commercialize biosimilars and generics, allowing them to avoid the risky process of clinical trials.
- Three companies report the market for product candidates is dominated by one or a few companies.

Theory predicts that the nature of the pharma R&D industry and current regulatory structure create incentives for large firms with downstream capacity to increasingly move resources out of upstream R&D, especially in the U.S., if they are able to purchase rights to the results of upstream R&D at lower cost than producing those R&D outputs themselves. Upstream competition can make it more profitable for large firms with a downstream presence to purchase patent rights rather than invest in their own upstream R&D, which Roy & King (2016) note is a common industry practice. Nonetheless, these hypothesized disincentives to R&D were seldom mentioned by industry experts (West et al., 2017b) or in the secondary literature (Anderson et al., 2017) or directly by firms. Five secondary sources (compared to one firm filing) describe private R&D efforts to improve the efficacy or effectiveness of existing treatments – so-called “me-too” drugs – as examples of private investors’ preference to secure downstream rents rather than invest in new health R&D ventures. The suggestion repeated in the literature that limited patent windows may encourage private firms to divert resources towards marketing rather than additional R&D in order to maximize profits during the period of exclusivity (Love, 2005) is not referenced in the 10-Ks.

Triangulating 10-Ks with Expert Interviews and Literature Findings

We find some corroboration between expert opinion as reported in West et al. (2017b) and in the review of literature undertaken by Anderson et al. (2017). West et al. (2017b) found six main factors reported by industry experts to explain limited global health private sector R&D: *Limited Markets for Certain Diseases* (illnesses that affect small numbers), the *Cost of Drug Development* (long development cycle), *Geo-political Risks* (risks to long-term investments and revenue streams), *Macroeconomic Difficulties* (recession, exchange rate, and interest rate risks), *Poor Health Governance* (difficulty in products reaching intended beneficiaries), and a *Lack*

of *Systematic Data* (evidence on what works). Anderson et al.'s (2017) review of literature as well as the current review of industry 10-Ks suggest that in the revenue calculation, LMIC pricing is the primary disincentive (even in cases where the LMIC market size is large), especially relative to drug pricing in the U.S. and other HICs. Limited market size was seldom mentioned as a deterrent among the 10-Ks we reviewed (9 out of 132 companies). Rather, company 10-Ks were more likely to cite challenges related to market competition, which were mentioned by 27 companies. Another common problem cited in company 10-Ks references downward pricing pressure and cost-containment from governments and other third-party payers in high income countries. Other factors cited by experts in West et al. (2017b) including *Geopolitical Risks*, *Macroeconomic Difficulties*, *Poor Health Governance*, and a *Lack of Systematic Data* are less frequently cited in the literature or 10-Ks as key determinants of private sector investment decisions - although all broadly relate to private firms' perceptions of risks and potential revenues associated with R&D investments.

Largely absent from factors highlighted in expert consultations but frequently mentioned in the literature is the effect of an imperfectly competitive market structure. This potentially grants larger pharmaceutical firms sufficient market power to buy or license R&D below a competitive market price (rather than conduct their own R&D) and enough market and regulatory influence to sell final products above a competitive market price. Patents, licensing, and royalties were mentioned by a majority of firms in the 10-K filings, with approximately half (65 out of 132) specifically mentioning purchasing licenses for R&D. Companies in the 10-K sample report that in-licensing occurs through all stages of drug development, with companies acquiring R&D to either fill gaps in their research during clinical development, or to commercialize and market after clinical trials have been completed. We find evidence that the current health R&D market structure is characterized - and likely constrained - by specialization, high entry costs, regulatory rents and privately held information; a result of both the nature of disease research and the policy environment.

Though a variety of policy tools exist to promote private sector investment in R&D, including push mechanisms (public research funding, R&D tax credits) and pull mechanisms (advance purchase commitments, orphan drug programs, priority review vouchers, wild-card patent extensions), evidence of effectiveness is mixed. Advanced purchase or market commitments (AMC) guarantee markets for new, viable products that can incentivize developing products for diseases with limited markets, but are mentioned by very few companies in our sample (four). Orphan drug status is most commonly applied by companies to Type 1 disease R&D. Expedited review policies mentioned include several aimed specifically at Type 2 or 3 diseases, though others such as "Fast Track" designation may also be applied to Type 1 disease R&D. The attractiveness of licensing upstream research rather than conducting it internally is likely to increase as more computing and data-based aspects of R&D occur in biotech companies relative to the physical science labs of traditional pharmaceutical companies.

Lastly, to the extent that health data are more limited for global health diseases, there is reason to speculate that as the industry shifts more R&D to biotechnology even less will be directed at diseases prevalent in LMICs. Both industry experts and the literature lament the limited market data available to assess potential market outcomes - yet despite potential industry-wide gains, there is no incentive for any individual firm to either fund or contribute to such a data service. We found some evidence in our review of 10-Ks that point to collaborations between companies, academic institutions, medical centers, or government agencies, although this was mentioned by only a relatively few (6 out of 71) companies that research Type 2 or 3 diseases.